

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
ALL CLASS ACTIONS

**BAYER CORPORATION'S ANSWER TO PLAINTIFFS'
AMENDED MASTER CONSOLIDATED CLASS ACTION COMPLAINT**

Defendant Bayer Corporation (“Bayer”), for its Answer to Plaintiffs’ Amended Master Consolidated Class Action Complaint (the “AMCC”), states:

Preliminary Statement

The AMCC improperly and repetitively refers to Bayer and certain other defendants and third parties on a collective basis, failing to plead with the requisite particularity allegations against Bayer. Intentionally ambiguous pleading is improper and insufficient to apprise Bayer in any meaningful sense of the allegations asserted against it. Bayer has nevertheless attempted to respond to Plaintiffs’ allegations to the extent possible under the circumstances. To the extent allegations refer to the knowledge, conduct, or actions of other defendants or entities, Bayer is generally without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Bayer denies those allegations. Bayer states that it is answering Plaintiffs’ allegations on behalf of itself only, even when Plaintiffs’ allegations refer to alleged conduct by Bayer and other persons or entities.

The AMCC improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the AMCC are vague or conclusory. The AMCC also includes terms which are undefined and which are susceptible of different meanings.

The AMCC also contains purported quotations from a number of sources, many of which are unidentified. If any of the quotations originate in documents protected by the attorney-client privilege, the work-product doctrine, or the joint-defense privilege, Bayer reserves the right to assert such privileges, hereby moves to strike such references, and demands return of any such documents that Plaintiffs may have in their possession, custody, or control. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

Bayer denies each and every allegation contained in the AMCC, except as specifically herein admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos, or speculations which are contained in any averment or in the AMCC as a whole. Moreover, Bayer specifically denies any allegations contained in headings, footnotes, the Table of Contents, or unnumbered paragraphs in the AMCC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

I. INTRODUCTION

1. Bayer admits that Plaintiffs seek to bring this action as alleged but denies that Plaintiffs are entitled to maintain it.
2. Bayer denies the allegations.
3. Bayer admits that at times relevant to this litigation it or its subsidiaries manufactured certain medicines that are covered under Medicare Part B and that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP. Bayer admits that at times relevant to this litigation it or its subsidiaries reported certain pricing information for medicines to independently produced pricing publications. Bayer denies the remaining allegations that pertain to it.
4. Bayer admits that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP, and further admits that Medicare Part B medicines are generally, but not always, administered in a healthcare provider's office. Bayer denies the remaining allegations.
5. Bayer denies the allegations.
6. Bayer admits that Plaintiffs purport to bring this action as alleged but denies the remaining allegations.
7. Bayer denies the allegations.
8. The allegations state legal conclusions to which no answer is required. Bayer denies the remaining allegations that pertain to it.
- 9-10. The allegations are directed to other defendants and require no response from Bayer. To the extent they are deemed to pertain to Bayer, they are denied.

11. Bayer admits that Plaintiffs have filed attachments. To the extent the allegations are deemed to pertain to Bayer, they are denied.

12. Bayer denies the allegations. Bayer further states that the Court dismissed Count I in its Order dated February 24, 2004.

13-21. Bayer admits that Plaintiffs purport to bring this action as a class action, and that Plaintiffs seek relief under Counts II through X as alleged in Paragraphs 13 through 21. Bayer denies that this action can be maintained in the manner alleged or that Plaintiffs are entitled to relief under Counts II through X.

II. JURISDICTION AND VENUE

22-23. To the extent the allegations state legal conclusions, no answer is required. Bayer denies the remaining allegations.

24. To the extent the allegations state legal conclusions, no answer is required. Bayer admits that Plaintiffs allege that venue is proper in this judicial district. Bayer denies the remaining allegations.

25. Bayer admits the allegations.

III. PARTIES

26-31. Bayer is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations and therefore denies them.

32-36. Bayer admits that Plaintiffs VPIRG, WCA, StateWide, CANY, and CCJ purport to bring this action as alleged in Paragraphs 32 through 36 but denies that these Plaintiffs have standing. Bayer is without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations and therefore denies them.

36(a)–(c). Bayer is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations and therefore denies them.

37-38. Bayer denies the allegations.

39-60. The allegations in Paragraphs 39 through 60 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

61. Bayer admits it is an Indiana corporation with its principal place of business located at 100 Bayer Road, Crafton, Pennsylvania. Bayer admits that it is a wholly owned United States subsidiary of a German corporation, Bayer AG. Bayer admits that its pharmaceutical subsidiary is located at 400 Morgan Lane, West Haven, Connecticut. Bayer denies the remaining allegations.

62. Bayer admits that at times relevant to this litigation it was a highly diversified health care company whose business included the development, manufacture, marketing, sale, and/or distribution of healthcare products and services, including pharmaceuticals. Bayer denies the remaining allegations.

63. Bayer admits that at times relevant to this litigation it or its subsidiaries manufactured Kogenate®, Kogenate®FS, Koate-®DVI, and Gamimune®N, which are used to treat hemophilia and/or immune system deficiencies and which are covered by Medicare Part B. Bayer denies the remaining allegations.

64-131. The allegations in Paragraphs 64 through 131 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

IV. GENERAL ALLEGATIONS APPLICABLE TO ALL DEFENDANTS

132. Bayer denies the allegations.

133. Upon information and belief, Bayer admits the allegations.

134-141. Bayer admits that Congress has mandated that Medicare Part B reimbursements be based, in part, upon AWP. Bayer admits that independently produced pricing publications periodically report AWPs for prescription medicines sold in the United States. Bayer states that the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 136 are the best evidence of their contents. Bayer denies the remaining allegations in Paragraphs 134 through 141.

142-144. Bayer admits the allegations in Paragraphs 142 through 144.

145. The allegations state legal conclusions to which no answer is required. Bayer admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth at 42 C.F.R. § 405.517, which is the best evidence of its contents. Bayer denies the remaining allegations.

146. Bayer denies the allegations in the first sentence insofar as the source of the quoted material is unidentified. Bayer denies the second sentence insofar as 42 C.F.R. § 405.517 contains no reference to a “ceiling” on reimbursement amounts.

147. Bayer admits the allegations.

148. Bayer admits that the Medicare Program has publicly announced that it would use the AWP published in independently produced pricing publications as the basis for reimbursement. Bayer states that the Program Memo AB-99-63 cited in Paragraph 148 is the best evidence of its contents.

149. Bayer states that the Program Memo AB-99-63 cited in Paragraph 149 is the best evidence of its contents.

150-151. Bayer admits the allegations.

152. Bayer admits that there are no government regulations describing how AWPs are calculated, nor any other statutory or regulatory definitions or descriptions of AWPs. Bayer admits that at times relevant to this litigation it or its subsidiaries reported certain pricing information for medicines to independently produced pricing publications. Bayer denies the remaining allegations.

153-154. Bayer denies that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to Bayer. Bayer states that the April 2003 OIG report cited in Paragraphs 153 through 154 is the best evidence of its contents.

155. Bayer admits that the DOJ and the OIG have previously investigated Bayer, among others, for practices relating to the calculation of AWP. Bayer denies the remaining allegations.

156-157. Bayer denies that Plaintiffs have accurately characterized the findings, opinions, statements or conclusions of Congressman Stark cited in Paragraphs 156 through 157, or that such are applicable to Bayer. Bayer states that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America is the best evidence of its contents.

158-159. To the extent that the allegations refer to parties other than Bayer, Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies the allegations. Bayer denies the allegations that pertain to it..

160. To the extent that the allegations refer to parties other than Bayer, Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies the allegations. Bayer admits that at times relevant to this litigation it or its subsidiaries have reported certain pricing information for medicines to independently produced pricing publications. Bayer denies the remaining allegations that pertain to it.

161-184. To the extent that the allegations in Paragraphs 161 through 184 refer to parties other than Bayer, Bayer is without knowledge or information sufficient to form a belief as to their truth or falsity and therefore denies the allegations. Bayer denies the allegations that pertain to it.

185. Bayer admits that Plaintiffs purport to quote from an unidentified “industry consultant” as alleged but denies the remaining allegations.

186-191. Bayer states that the *Red Book* and the unidentified DOJ report cited in Paragraph 187 and the pleadings cited in Paragraphs 189 through 190 and subparts are the best evidence of their contents. Bayer denies the remaining allegations.

192. Bayer states the 2003 CMS document cited in Paragraph 192 is the best evidence of its contents. Bayer denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement, or conclusion. Bayer admits that at times relevant to this litigation it or its subsidiaries sold medicines in a competitive market and, as such, took steps to keep certain information relating to their medicines confidential. Bayer denies the remaining allegations.

193-196. Bayer denies the allegations in Paragraphs 193 through 196.

197. Bayer denies the allegations.

198-199. The allegations state legal conclusions to which no response is required.

V. EXAMPLES OF SPECIFIC UNLAWFUL CONDUCT

200. Bayer denies the allegations.

201-285. The allegations in Paragraphs 201 through 285 of the AMCC are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

286. Bayer admits that Plaintiffs purport to bring this action as alleged but denies that Plaintiffs are entitled to a judgment or any relief. Bayer denies the remaining allegations.

287. Bayer admits that the governmental agencies listed in Paragraph 287 have conducted investigations concerning pricing in the pharmaceutical industry and that Bayer, among others, previously participated in such investigations. Bayer admits that it agreed to settle claims asserted by the United States government and 47 states. Bayer states that the January 23, 2001 DOJ press release cited in Paragraph 287 is the best evidence of its contents. Bayer denies the remaining allegations.

288. Bayer states that the settlement of government claims and the corporate integrity agreement cited in Paragraph 288 are the best evidence of their contents. Bayer otherwise denies the allegations.

289. Bayer admits that in April 2003, it agreed to pay the government \$251.6 million but denies the remaining allegations.

290. Bayer admits that it produced the document cited in Paragraph 290 (BAY005278), but states that the document is the best evidence of its contents and denies that the conclusions Plaintiffs draw from the document are accurate. Bayer denies the remaining allegations.

291. Bayer denies that it produced the document cited in Paragraph 291 (P007549) and states that the September 28, 2000 letter from Representative Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America, is the best evidence of its

contents. Bayer denies that the conclusions drawn by Plaintiffs are accurate. Bayer denies the remaining allegations.

292. Bayer states that the September 25, 2000 letter from Tom Bliley to the Health Care Financing Administration cited in Paragraph 292 is the best evidence of its contents.

293-294. Bayer denies that it produced the documents cited in Paragraphs 293 and 294 and states that the report published by the DHHS (AB-00-86 (P006299-006316)) cited in Paragraph 293 of AMCC and the report published by the OIG (OEI-03-00-00310 (P006398-006424)) cited in Paragraph 294 of the AMCC are the best evidence of their contents. Bayer denies that Plaintiffs have accurately characterized any alleged finding, opinion, statement, or conclusion contained in these documents. Bayer denies the remaining allegations.

295. Bayer admits that Kogenate® was among the medicines at issue in its 2001 settlement with the government, but states that the government settlement cited in Paragraph 295 is the best evidence of its contents. Bayer denies the remaining allegations.

296. Bayer admits that at times relevant to this litigation it or its subsidiaries have sold medicines at prices lower than the published AWP for those medicines. Bayer denies the remaining allegations.

297. Bayer denies the allegations.

298. Bayer denies that it produced the document cited in Paragraph 298 and states that the October 1, 1996 memorandum is the best evidence of its contents. Bayer denies that Plaintiffs have accurately characterized any alleged document, finding, opinion, statement, or conclusion.

299-301. Bayer denies the allegations in Paragraphs 299 through 301.

302-540. The allegations in Paragraphs 302 through 540 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

VI. PLAINTIFFS' CLAIM FOR DAMAGES

541. Bayer denies the allegations.

VII. PLAINTIFFS' CLAIMS CONCERNING TOGETHER RX

542-594. The allegations in Paragraphs 542 through 594 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

VIII. CLASS ALLEGATIONS FOR THE PURPORTED "AWP PAYOR CLASS"

595-598. Bayer admits that Plaintiffs purport to bring this action as alleged in Paragraphs 595 through 598 but denies that Plaintiffs are entitled to maintain it. Bayer denies that Plaintiffs or any putative class members have suffered damages.

599-603. The allegations in Paragraphs 599 through 603 state legal conclusions to which no answer is required. Bayer denies, however, that Plaintiffs have pled a proper class, named proper class representatives, or suffered damages or injuries.

IX. CLASS ALLEGATIONS FOR THE PURPORTED "TOGETHER RX CLASS"

604-618. The allegations in Paragraphs 604 through 618 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

COUNT I (RICO)

619-646. The Court dismissed Count I in its Order dated February 24, 2004.

Accordingly, no response is required.

COUNT II (RICO)

647. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 646.

648. Bayer admits that Plaintiffs purport to bring this action and to seek relief under Count II as alleged but denies that Plaintiffs are entitled to maintain this action or to seek any relief against Bayer under Count II. Bayer denies the remaining allegations.

649. The allegations state a legal conclusion to which no answer is required. Bayer denies, however, that Plaintiffs have pled a proper class.

650. To the extent the allegations state legal conclusions, no answer is required. Bayer denies the remaining allegations.

651-655. Bayer states that the unidentified "industry report" cited in Paragraph 655 is the best evidence of its contents. Bayer denies that Plaintiffs have accurately characterized any alleged "industry report" finding, opinion, statement, or conclusion. Bayer denies the remaining allegations.

656-678. Bayer denies the allegations in Paragraphs 656 through 678.

679. The allegations state legal conclusions to which no answer is required.

COUNT III (DECLARATORY RELIEF)

680. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 679.

681. To the extent the allegations state legal conclusions, no answer is required. Bayer denies the remaining allegations.

682-683. Bayer refers to and incorporates its response to Paragraph 681. Bayer denies the remaining allegations.

COUNT IV (CONSUMER PROTECTION STATUTES)

684. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 683.

685. Bayer admits that Plaintiffs purport to bring this action and to seek relief under Count IV as alleged but denies that Plaintiffs are entitled to maintain this action or to seek any relief against Bayer under Count IV. Bayer denies the remaining allegations.

686. Bayer admits that its principal place of business is located in Crafton, Pennsylvania. Bayer admits that certain states have enacted consumer protection laws, but Bayer denies that it has violated such laws or that Plaintiffs or any putative class members are entitled to relief under such laws. Bayer denies the remaining allegations.

687-691. Bayer denies the allegations in Paragraphs 687 through 691. Bayer further denies that Plaintiffs or any putative class members have suffered damages or injuries.

COUNT V (CLAYTON ACT – TOGETHER RX)

692-698. The allegations in Paragraphs 692 through 698 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

COUNT VI (SHERMAN ACT – TOGETHER RX)

699-704. The allegations in Paragraphs 699 through 704 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

COUNT VII (INDIRECT PURCHASER – TOGETHER RX)

705-708. The allegations in Paragraphs 705 through 708 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

COUNT VIII (RICO – TOGETHER RX)

709-725. The allegations in Paragraphs 709 through 725 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

COUNT IX (CIVIL CONSPIRACY – PBMs)

726. Bayer realleges and incorporates its responses to the allegations in Paragraphs 1 through 725.

727. Bayer admits that Plaintiff CMHV purports to bring this action as alleged but denies that Plaintiff CMHV is entitled to maintain this action or that CMHV is a proper class representative. Bayer denies the remaining allegations.

728-731. Bayer denies the allegations in Paragraphs 728 through 731.

732-733. Bayer denies the allegations. Specifically, Bayer denies that Plaintiffs or any putative class members have suffered damages or injuries.

COUNT X (CIVIL CONSPIRACY – TOGETHER RX)

734-741. The allegations in Paragraphs 734 through 741 are directed to other defendants and require no response from Bayer. To the extent the allegations are deemed to pertain to Bayer, they are denied.

UNNUMBERED “WHEREFORE” PARAGRAPH AND REQUEST FOR JURY TRIAL

Bayer denies Plaintiffs are entitled to a judgment or any other relief requested in their Prayer for Relief and “WHEREFORE” paragraph.

DEFENSES

First Defense

Plaintiffs and the putative class fail to state a claim against Bayer upon which relief may be granted.

Second Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the political question and separation of powers doctrines.

Third Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the filed rate doctrine.

Fourth Defense

Plaintiffs and the putative class have not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of Bayer as alleged.

Fifth Defense

To the extent Plaintiffs and/or any member of the putative class obtain recovery in any other case predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against Bayer pursuant to the doctrines of res judicata and collateral estoppel, and the prohibition on double recovery for the same injury.

Sixth Defense

Plaintiffs’ and the putative class’ claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitutions

of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington and any other States whose laws are or become relevant in the course of this multidistrict litigation.

Seventh Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or conduct by Bayer in judicial, legislative, or administrative proceedings of any kind or at any level of government.

Eighth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction, or otherwise compromised their claims.

Ninth Defense

Any and all actions taken by Bayer with respect to any of the matters alleged were taken in good faith and in accordance with established industry practice.

Tenth Defense

Plaintiffs' and the putative class' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

Eleventh Defense

Plaintiffs' and the putative class' claims are preempted by the Commerce Clause of the United States Constitution.

Twelfth Defense

Plaintiffs' and the putative class' claims against Bayer are barred because Bayer has complied with all applicable regulations of the federal and state governments.

Thirteenth Defense

Plaintiffs' and the putative class' claims against Bayer are barred, in whole or in part, by the applicable statutes of limitations and repose and by the doctrines of laches, estoppel, and waiver.

Fourteenth Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because they violate Bayer's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as all applicable state constitutions, insofar as Plaintiffs and the putative class members seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

Fifteenth Defense

Bayer's statements or actions were not the proximate cause or cause in fact of any injury to or alleged loss by Plaintiffs or the putative class.

Sixteenth Defense

Plaintiffs and the putative class fail to state with particularity facts to support the fraud allegations and to plead with particularity the fraudulent concealment and multi-source medicine allegations against Bayer.

Seventeenth Defense

Plaintiffs and the putative class fail to allege with particularity their civil conspiracy claims against Bayer as required by Fed. R. Civ. P. 9(b).

Eighteenth Defense

Plaintiffs' and the putative class' claims against Bayer are barred, in whole or in part, because Bayer did not make any false statements to Plaintiffs or to any members of the putative class. As to any statement asserted against Bayer that Plaintiffs and the putative class allege to be false or misleading, Bayer had no reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

Nineteenth Defense

Plaintiffs' and the putative class' claims against Bayer are barred because Bayer did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

Twentieth Defense

Plaintiffs' and the putative class' RICO claims against Bayer are barred, in whole or in part, due to Plaintiffs' failure to properly allege a RICO enterprise as required by 18 U.S.C. § 1962(c).

Twenty-First Defense

Plaintiffs' and the putative class' RICO claims against Bayer are barred, in whole or in part, due to their failure to plead facts showing that Bayer and the PBMs are ongoing organizations whose members function as a continuing unit and share common purposes as required by *United States v. Turkette*, 452 U.S. 576, 583 (1981).

Twenty-Second Defense

Plaintiffs' and the putative class' RICO claims against Bayer are barred, in whole or in part, due to their failure to allege that Bayer conducted the affairs of the alleged enterprises as required by 18 U.S.C. § 1962(c).

Twenty-Third Defense

Plaintiffs and the putative class lack standing to bring their RICO claims against Bayer because they cannot show Bayer directly caused their alleged injuries as required by 18 U.S.C. § 1964(c) and *Holmes v. Securities Investor Prot. Corp.*, 503 U.S. 258, 265-66, 268 (1992).

Twenty-Fourth Defense

Plaintiffs' and the putative class' civil conspiracy claims against Bayer are barred, in whole or in part, by their failure to allege a concerted action as required by *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1564 (1st Cir. 1994) and *Grant v. John Hancock Mut. Life Ins. Co.*, 183 F. Supp. 2d 344, 359 (D. Mass. 2002) and/or by their failure to allege a coercive conspiracy as required by *Fleming v. Dance*, 22 N.E.2d 609, 611 (Mass. 1939).

Twenty-Fifth Defense

Plaintiffs' and the putative class' civil conspiracy claims against Bayer are barred, in whole or in part, because they are duplicative and improper under Massachusetts law. See *Grant*, 183 F. Supp. 2d at 364.

Twenty-Sixth Defense

Bayer denies that Plaintiffs and the putative class have valid consumer protection claims against Bayer under the law of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington, or any other State whose law is or becomes relevant in the course of this multidistrict litigation. However, if such claims are found to exist, Bayer pleads all available defenses under the Acts.

Twenty-Seventh Defense

Any allegedly fraudulent statements or conduct of Bayer did not directly or proximately cause the alleged injuries of Plaintiffs and/or any members of the putative class as required under state consumer protection laws, including without limitation those of Florida, Illinois, Louisiana, New Jersey, New York, Pennsylvania, Texas, and Washington.

Twenty-Eighth Defense

Bayer's conduct was neither "deceptive," "misleading," "unlawful," nor "illegal" as required under certain state consumer protection laws, including without limitation those of Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Texas, and/or Washington.

Twentieth-Ninth Defense

To the extent that Plaintiffs and the putative class members attempt to seek equitable relief against Bayer, they are not entitled to such relief because they have an adequate remedy at law.

Thirtieth Defense

Plaintiffs and the putative class lack standing to bring their asserted consumer protection claims against Bayer under certain state consumer protection laws, including without limitation those of Delaware, Florida, Louisiana, New Jersey, Pennsylvania, and Washington.

Thirty-First Defense

Plaintiffs and the putative class did not rely on the allegedly fraudulent statements or conduct of Bayer as required under certain state consumer protection laws, including without limitation those of New York and Pennsylvania.

Thirty-Second Defense

Any allegedly fraudulent statement or conduct of Bayer was not consumer-oriented as required under certain consumer protection laws, including without limitation that of New York.

Thirty-Third Defense

Plaintiffs' and the putative class' claims against Bayer under the various state consumer protection and consumer fraud statutes are barred in whole or in part to the extent those statutes: (1) do not allow (or did not allow at the time the conduct was alleged herein) recovery of damages by indirect purchasers; and (2) do not govern conduct that is predominantly interstate in nature.

Thirty-Fourth Defense

Plaintiffs' and the putative class' claims against Bayer for injunctive relief were mooted by the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

Thirty-Fifth Defense

Plaintiffs' and the putative class' claims for injunctive relief against Bayer are barred by the doctrines of *in pari delicto* and/or unclean hands.

Thirty-Sixth Defense

This action cannot be maintained as a class action because: (1) the certification and maintenance of this action as a class would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch; (2) the claims of Plaintiffs and the putative class cannot be properly joined with one another because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences; (3) the named Plaintiffs and the putative class cannot satisfy the procedural requirements of Fed. R. Civ. P. 23; (4) the questions of fact at issue are not common

to the alleged class, but rather, are highly specific and will vary dramatically from person to person and entity to entity; and/or (5) class certification would violate Bayer's rights provided by the Fifth, Seventh, and Fourteenth Amendments to the United States Constitution as well as by the Constitutions of the States of California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington, and any other States whose laws are or become relevant in the course of this multidistrict litigation, including but not limited to Bayer's right to procedural and substantive safeguards, which include traditional defenses to liability.

Thirty-Seventh Defense

Third party payor plaintiffs' and third party payor putative class members' claims against Bayer are barred, in whole or part, with respect to any alleged overcharge or on the ground that third party payors passed on any effect of the alleged inflated prices to their customers or employees in the form of higher premiums.

Thirty-Eighth Defense

Plaintiffs' and the putative class' claims against Bayer are barred, in whole or in part, with respect to any alleged overcharge because such overcharge, if any, was absorbed, in whole or part, by a person and/or entity which purchased the medicine directly, and/or by an intermediate indirect purchaser, and was not passed on to the Plaintiffs and putative class members.

Thirty-Ninth Defense

Plaintiffs' and the putative class' claims against Bayer are barred, in whole or in part, due to their failure to join indispensable parties.

Fourtieth Defense

Plaintiffs' and the putative class' claims against Bayer are barred, in whole or in part, because they have suffered no damages.

Forty-First Defense

Plaintiffs' and the putative class' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties.

Forty-Second Defense

Plaintiffs' and the putative class' claims against Bayer for damages are barred, in whole or in part: (1) because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Bayer; (2) because they would be unjustly enriched if allowed to recover; (3) by the doctrine of consent and/or ratification to the extent that plaintiffs and/or putative class members have received and paid for medicines manufactured, marketed and sold by Bayer or its subsidiaries after the filing of Plaintiffs' original Complaint; and (4) because they are speculative and remote and because of the impossibility of ascertaining and allocating the damages.

Forty-Third Defense

Bayer is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs and/or the putative class, with respect to the same injuries.

Forty-Fourth Defense

Any damages recovered by the Plaintiffs and the putative class from Bayer must be limited by the applicable statutory ceilings on recoverable damages.

Forty-Fifth Defense

Plaintiffs and the putative class fail to allege facts or a cause of action against Bayer sufficient to support a claim for attorneys' fees, treble damages, and/or legal fees.

Forty-Sixth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' punitive damages claims against Bayer: (1) have no basis in law or fact; (2) are not recoverable because the allegations are legally insufficient to support a claim for punitive damages against Bayer; and (3) cannot be sustained because: (i) laws regarding the standards for determining liability for and the amount of punitive damages fail to give Bayer prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of Bayer's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the constitutions of any applicable states' laws; (ii) an award of punitive damages would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, statutes, and public policy of any applicable states' laws; (iii) an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against Bayer for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of Bayer's medicines would constitute impermissible multiple punishments for the same wrong, in violation of Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the constitutions, common law, and statutory law of any applicable states' laws; (iv) any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the

alleged percentage of the wrong committed by each alleged tortfeasor, would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable states' law; and (v) any award of punitive damages, which are penal in nature, without according Bayer the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against self-incrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate Bayer's rights guaranteed by the Fourth, Fifth, and Sixth Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable states' laws.

Forty-Seventh Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against Bayer cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part on the basis of invidiously discriminatory characteristics, including without limitation the residence, wealth, and corporate status of Bayer; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes

punitive damages permissible; (5) is not properly instructed regarding Plaintiffs' and the putative class' burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate Bayer's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the constitutions, common law, and public policies of any applicable states' laws.

Forty-Eighth Defense

To the extent punitive damages are sought, Plaintiffs' and the putative class' claim for punitive damages against Bayer cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would: (1) violate Bayer's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate Bayer's right not to be subject to an excessive award; and (3) be improper under the constitutions, common law, and public policies of any applicable states' laws.

Forty-Ninth Defense

Bayer adopts by reference any additional applicable defense pled by any other defendant not otherwise pled herein.

Fiftieth Defense

Bayer hereby gives notice that it intends to rely upon any additional defense that is now or may become available or appear during or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Bayer also reserves the right to assert such other and related defenses as may become available in the event

of a determination that the action, or some part thereof, is governed by the substantive law of a state other than California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, Washington, and/or any other State whose law is or becomes relevant in the course of this multidistrict litigation.

WHEREFORE, Bayer prays that this Court:

1. Dismiss the Amended Master Consolidated Class Action Complaint with prejudice and enter judgment in its favor and against Plaintiffs;
2. Award Bayer its costs and expenses; and
3. Grant such other and further relief as this Court deems just and proper.

By /s/ Robert P. Sherman
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CERTIFICATE OF SERVICE

I hereby certify that on this 9th day of April, 2004, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.

/s/ Marisa L. Jaffe
Attorney for Defendant Bayer Corporation